

April 24, 2025

VIA ELECTRONIC FILING

Hon. Philip M. Halpern
Southern District of New York
300 Quarropas St., Courtroom 520
White Plains, NY 10601

Application granted. The unredacted document (Doc. 179) shall remain under seal, and the redacted document shall remain the publicly-filed version (Doc. 180).

SO ORDERED.



Philip M. Halpern
United States District Judge

Dated: White Plains, New York
April 24, 2025

Re: *Regeneron Pharmaceuticals, Inc. v. Novartis Pharma AG et al.*, No. 7:20-cv-05502 (PMH) (S.D.N.Y.) – Joint Letter Motion to Seal Exhibits to Joint Pre-Motion Letter

Dear Judge Halpern:

Plaintiff Regeneron Pharmaceuticals, Inc. (“Regeneron”) and Defendants Novartis Pharma AG, Novartis Technology LLC, and Novartis Pharmaceutical Corp. (collectively, “Novartis”) are prepared to submit a joint pre-motion letter (the “Pre-Motion Letter,” or, “Letter”) respectfully requesting a conference concerning Regeneron’s assertion that Novartis has waived privilege as to all documents and communications concerning its investigation and analysis of Vetter’s inventorship claim regarding U.S. Patent No. 9,220,631 (“the ’631 patent”). In accordance with Rule 5(B) of Your Honor’s Individual Practice Rules, the Standing Order In Re: Electronic Filing Under Seal in Civil and Miscellaneous Cases (19-mc-00583), and ECF Rules & Instructions Sections 6 and 21, Regeneron and Novartis write to request permission to file the Pre-Motion Letter and exhibits identified below under seal or in redacted form. Pursuant to Rule 5(B) of Your Honor’s Individual Practice Rules, the Pre-Motion Letter and below-identified exhibits are contemporaneously filed under seal.

A district court “has supervisory power over its own records and files,” and public access to these records and files “has been denied where court files might have become a vehicle for improper purposes.” *Nixon v. Warner Commc’ns, Inc.*, 435 U.S. 589, 598 (1978). While “[t]here is a common law presumption in favor of permitting public access to judicial documents,” a “court balances this common law presumption of access against competing comparisons, including the

privacy interests of those resisting disclosure.” *GoSMiLE, Inc. v. Dr. Jonathan Levine, D.M.D. P.C.*, 769 F. Supp. 2d 630, 649 (S.D.N.Y. 2011) (citing *Lugosch v. Pyramid Co. of Onondaga*, 435 F.3d 110, 119 (2d Cir. 2006)). Competitively sensitive information, for example, should be protected against public disclosure if such disclosure would cause significant and irreparable competitive injury. *See, e.g., Standard Inv. Chartered, Inc. v. Fin. Indus. Reg. Auth.*, 347 F. App’x 615, 617 (2d Cir. 2009) (finding that presumption of public access was overcome when disclosure would subject a party to financial harm and cause significant competitive disadvantage).

Among the exhibits attached to the joint letter is Exhibit 14, an excerpted version of the ITC deposition transcript of Daniel Van Plew, Executive Vice President and General Manager of Industrial Operations and Product Supply at Regeneron. Mr. Van Plew’s deposition transcript has been produced in this case and designated as “CONFIDENTIAL BUSINESS INFORMATION” pursuant to the Protective Order. *See* Dkt. 76. Regeneron seeks to seal Exhibit 14. The sealing of Exhibit 14 is narrowly tailored to protect commercially sensitive and confidential information, including testimony on non-public patent sublicense offers and corresponding strategic business and commercial development decisions. Importantly, disclosure of this confidential business information would likely result in competitive harm to Regeneron. For example, disclosure of the economic terms of the parties’ various licensing and/or commercial agreements could disadvantage them in future negotiations with third parties with respect to similar agreements. *See, e.g., Graczyk v. Verizon Commc’ns, Inc.*, No. 18-6465, 2020 WL 1435031, at *8-9 (S.D.N.Y. Mar. 24, 2020) (granting party’s request to seal portions of contracts that contained “sensitive financial information” that would cause them to suffer “competitive disadvantage in future negotiations”). To protect parties from harm of this nature, courts in this Circuit have generally exercised their discretion to seal judicial records. *See, e.g., KeyBank Nat’l Ass’n v. Element Transp.*

LLC, No. 16-8958, 2017 WL 384875, at *3 (S.D.N.Y. Jan. 26, 2017) (“KeyBank asserts that the sensitive nonparty financial information it seeks to protect is all the data a competitor would need to determine its valuation of the leases. This competitive injury is sufficiently serious to warrant protection.”). In contrast, there is no benefit to the public from disclosure of the confidential information sought to be sealed here. Thus, the competitive disadvantages that would flow to Regeneron if such information was disclosed outweighs the interest of the public, including competitors, of viewing those specific terms. *See Lugosch*, 435 F.3d at 120.

Fourth Lucentis Development Agreement and Related Documents. The Fourth Lucentis Development Agreement (Exhibit 2) is a contract between Novartis and Vetter that contains commercially sensitive terms, including the terms on which the parties agreed to resolve Vetter’s claim that it had an ownership interest in the ’631 Patent. The confidential terms on which the parties agreed would be valuable to Novartis’s current or future competitors and/or counterparties in similar negotiations with Novartis and therefore should be sealed. *See, e.g., United States v. Amodeo*, 71 F.3d 1044, 1051 (2d Cir. 1995) (“Commercial competitors seeking an advantage over rivals need not be indulged in the name of monitoring the courts . . .”). The Fourth Lucentis Development Agreement contains detailed and commercially sensitive provisions, including provisions regarding royalty rates and specific licensing and sublicensing terms, that, if disclosed, would harm Novartis by providing future counterparties with insights into how, and on what terms, agreements could be reached, that those counterparties otherwise would not have. This potential competitive harm to Novartis warrants sealing. *See id.*; *Rubik’s Brand Ltd. v. Flambeau, Inc.*, 2021 U.S. Dist. LEXIS 53529 at *2-3 (S.D.N.Y. March 22, 2021) (granting motion to seal documents containing the terms of confidential agreements and noting that “[d]isclosure of these contractual terms could harm [the party’s] and/or its business partners by disadvantaging

them in negotiating future licensing agreements. Indeed, courts in this District have granted motions to seal in order to protect these sorts of competitive interests.”) (citation omitted); *Fairstein v. Netflix Inc.*, 2024 U.S. Dist. LEXIS 93867, at *3 (S.D.N.Y. May 21, 2024) (“The presumption of public access in filings submitted in connection with discovery disputes or motions *in limine* is generally somewhat lower than the presumption applied to material introduced at trial, or in connection with dispositive motions such as motions for dismissal or summary judgment.”).

Exhibits 1, 9, 10, and 11 are directly related to Novartis and Vetter’s agreements predating the Fourth Lucentis Development Agreement and reflect confidential and commercially sensitive negotiations between Novartis and Vetter leading up to the execution of the agreement. Additionally, Exhibit 13 contains excerpts of Novartis’s response to interrogatories that seek information about those negotiations, Novartis’s position in its dispute with Vetter, and Novartis’s development of Lucentis PFS in conjunction with Vetter. All of these exhibits are properly filed under seal in connection with the parties’ discovery dispute. *See Rubik’s Brand*, 2021 U.S. Dist. LEXIS 53529, at *3-4 (granting motion to seal documents containing information about “development . . . strategies”). For example, Exhibit 11 contains “Novartis Commentary on Vetter’s mark-up and Novartis updated amendment.” This document thus speaks to Novartis’s analysis and strategy as to a draft agreement that preceded the parties’ executed agreement, which warrants sealing. *See Vellali v. Yale Univ.*, 2021 U.S. Dist. LEXIS 192336, at *4-6 (D. Conn. Sept. 30, 2021) (“business strategies” are properly filed under seal; granting motion to seal where “disclosure of the information would interfere with [the party’s] present contracts with other clients the terms of which were the product of private negotiations”).

Documents For Which Privileged Is Disputed. Regeneron argues in the pre-motion letter that Novartis waived privilege through an interrogatory response (Exhibit 3) and deposition

testimony of David Spinner (Exhibits 4 and 12). While Novartis does not agree that these excerpts contain privileged information, to the extent the Court ultimately disagrees with Novartis's good-faith analysis and determines they are privileged, there is an interest in maintaining them under seal to prevent the disclosure of privileged information. *See Novartis Int'l Pharm. AG v. Incyte Corp.*, 2024 U.S. Dist. LEXIS 135547, at *3 (S.D.N.Y.) (recognizing that the "countervailing interest of preserving the privilege outweighs the presumption of public access" (citing *In re Agent Orange Prod. Liab. Litig.*, 98 F.R.D. 539, 545 (E.D.N.Y. 1983) ("Where unsealing of documents might reveal material governed by the work product privilege or the contents of communications between an attorney and client might be disclosed, the public interest in protecting those privileges would take precedence over its interest in inspecting and copying court records."))).

Additionally, Exhibits 5, 6 and 7 are discovery letters exchanged by Regeneron and Novartis prior to filing the Pre-Motion Letter. Each contains references to the material that Regeneron claims revealed privileged information and is subject to sealing for the reasons stated herein. Thus, for the same reasons that the Court should allow Novartis's interrogatory response and the Spinner testimony to be filed under seal, Novartis and Regeneron should also be permitted to file redacted versions of the discovery letters that redact the portions of those letters that refer to otherwise sealed exhibits. If the Court agrees with Novartis and holds that these materials are not privileged, Novartis would not object to re-filing Exhibits 3, 4, 5, 6, 7, and 12 in unredacted form.¹

¹ Exhibit 12 contains, on page 189, confidential information concerning the development of Lucentis PFS, and sealing is warranted to prevent disclosure of that information. *See Rubik's Brand Ltd.*, 2021 U.S. Dist. LEXIS 53529, at *2-3. Novartis would thus propose to re-file Exhibit 12 with only this excerpt redacted.

Pre-Motion Letter. Finally, the Pre-Motion Letter itself quotes from certain of the exhibits that Novartis requests to file under seal. Accordingly, the Court should permit Novartis to file on the public docket a version of the Pre-Motion Letter that redacts references to materials filed under seal, for the same reasons that the underlying exhibits should be filed under seal.

Accordingly, courts in this District routinely seal documents to prevent the disclosure of a party's confidential or competitively sensitive business information. *See, e.g., PDV Sweeny, Inc. v. ConocoPhillips Co.*, No. 14-5183 (AJN), 2014 WL 4979316, at *3 (S.D.N.Y. Oct. 6, 2014) (granting motion to seal "with respect to those documents...containing sensitive commercial information affecting the parties' ongoing relationship"); *Louis Vuitton Malletier S.A. v. Sunny Merch. Corp.*, 97 F. Supp. 3d 485, 511 (S.D.N.Y. 2015) (granting motion to redact documents containing advertising expenditures and plans, merchandising strategies, policies, and sales); *Playtex Prods., LLC v. Munchkin, Inc.*, No. 14- 1308, 2016 WL 1276450, at *11 (S.D.N.Y. Mar. 29, 2016) (granting request to seal documents concerning "Playtex's (i) sales and revenue, (ii) analytical testing of the Diaper Genie Refills, (iii) qualitative market research, and (iv) research and development for new products").

For the reasons stated above, Regeneron and Novartis respectfully requests that the Court grant its motion and allow Regeneron and Novartis to file the Pre-Motion Letter and above-identified exhibits to the Pre-Motion Letter under seal or in redacted form.

Respectfully Submitted,

/s/ Anish R. Desai

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